

United States Environmental Protection Agency (U.S. EPA) Science Advisory Board (SAB)
Quality Review Teleconference
December 16, 2010

Summary Minutes

Date and Time December 16, 2010, 1:00-4:00 p.m. Eastern Time

Location: By teleconference

Purpose: To conduct a quality review of a draft SAB report, *Review of EPA's Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures (February 2010 Draft)*¹

Meeting Participants:

SAB Members

Dr. Deborah Swackhamer, Chair
Dr. David Allen
Dr. Timothy Buckley
Dr. Ingrid Burke
Dr. Thomas Burke
Dr. Terry Daniel
Dr. George Daston
Dr. Costel Denson
Dr. David Dzombak
Dr. John Giesey
Dr. James Hammitt
Dr. Bernd Kahn
Dr. Agnes Kane
Dr. Nancy Kim
Dr. Kai Lee
Dr. Cecil Lue-Hing
Dr. Lee D. McMullen
Dr. Judith Meyer
Dr. Horace Moo-Young
Dr. Eileen Murphy
Dr. Duncan Patten

Dr. Stephen Roberts
Dr. James Sanders
Dr. Kathleen Segerson
Dr. Paige Tolbert
Dr. John Vena
Dr. Thomas Zoeller

Liaison Members

Dr. James Johnson
(EPA's National Advisory Council for Environmental Policy and Technology)

Other Participants:

SAB Staff Office

Dr. Thomas Armitage, Designated Federal Officer (DFO)

EPA

Dr. Lynn Flowers, EPA Office of Research and development

Other

Nancy Beck, Office of Management and Budget

Bridget DiCosmo, Risk Policy Report

Katy O. Goyak, ExxonMobil Biomedical Sciences, Inc

Katharine Kurtz, Navy and Marine Corps Public Health Center

Anita K. Meyer, U.S. Army Corps of Engineers

Resha M. Putzrath, Navy and Marine Corps Public Health Center

Vera Wang, Navy and Marine Corps Public Health Center

Kimberly Wise, American Petroleum Institute

Teleconference Summary:

Convene the meeting

Dr. Thomas Armitage, SAB DFO, convened the advisory meeting and welcomed the group. He noted that no requests had been received to provide oral public comments and that written public comments had not been received. He noted that meeting materials were available on the SAB Web site and that these included: the Federal Register notice announcing the meeting², meeting agenda³, and members' preliminary quality review comments⁴.

Purpose of meeting and review of the agenda

Dr. Deborah Swackhamer, the SAB Chair, welcomed SAB members and reviewed the purpose of the meeting. She reminded SAB members that quality reviews focus on four questions:

1. Were the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?
2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the Committee's report?
3. Is the Committee's report clear and logical?
4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Overview of draft Report

Dr. Nancy Kim, Chair of the SAB Polycyclic Aromatic Hydrocarbon (PAH) Mixtures Review Panel, provided an overview of the draft report. She noted that EPA's current approach to assessing cancer risk for PAHs utilized a relative potency factor approach which estimates cancer risks of individual PAHs relative to benzo[a]pyrene (BaP). She indicated that EPA had updated relative potency factors for some PAH's and had developed new relative potency factors for others as described in the Agency's draft document, *Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures*. She noted that the EPA had asked the SAB to provide recommendations on the scientific soundness and rationale of the Agency's draft document. She then summarized the Panel's responses to the EPA's nine charge questions as presented in the executive summary of the Panel's draft report.

EPA Comments

Dr. Lynn Flowers of EPA's Office of Research and Development thanked the Panel for its work and provided several comments on the Panel's draft report. She noted that EPA had begun work to update the cancer slope factor for BaP and that the timeline for this work will catch up to the RPF document. She also noted that the draft report indicated that the Panel agreed with EPA's use of the RPF approach but did not recommend calculating an RPF when only a single dose of the target PAH and BaP were available, or when data were from non-physiological routes of exposure. She noted that this recommendation would limit the number of RPFs that could be calculated.

Dr. Kim noted that, as indicated in the executive summary of the report, the Panel recognized the pragmatic need for the RPF approach and supported increasing the number of compounds in the approach. She indicated that she would look at the report to determine whether clarification was needed.

Chartered SAB Discussion

Dr. Swackhamer identified the lead reviewers to begin the SAB discussion. She noted that all of the lead reviewers had provided written comments; however, Dr. Jana Milford was not able to be on the call. She stated that she would summarize Dr. Milford's comments.

Dr. Stephen Roberts highlighted his written comments. He commented that the Panel had conducted a careful and thorough review of a large and complex report and had responded to multi-part charge questions. He offered several suggestions to clarify the Panel's report. He noted that some parts of the charge question responses did not appear to be mentioned in the executive summary and that it would be helpful to include this information in the executive summary. He noted that two aspects of the report needed some additional explanation. These were the criticism of the assumption of a common mode of action and the recommendation that EPA pursue a whole mixtures approach. He noted that the terms "mode of action" and "mechanism of action" were not always used correctly in the review document. He also noted the complexity of using a mixtures approach, and indicated that additional explanation of the use

of this approach should be provided. He indicated that some information in the response to the first charge question was beyond the scope of the question and should be moved into the other responses.

Dr. Paige Tolbert indicated that the Panel had provided a thoughtful and thorough response to each charge question. She noted that the report was clear and logical and indicated that she had provided some editorial comments to further clarify parts of the report. She noted that, overall, the conclusions and recommendations in the Panel's report were scientifically sound and supported by material in the body of the report.

Dr. Eileen Murphy agreed that the Panel had provided thoughtful and insightful recommendations in response to the charge questions. She found the report to be clear and logical and she provided some editorial comments to clarify parts of the report. She agreed with comments from Dr. Roberts and others indicating that additional explanation of the use of the mixtures approach was needed.

Dr. Swackhamer summarized the written comments of Dr. Jana Milford. Dr. Swackhamer noted that Dr. Milford found that the Panel's report had adequately addressed the charge questions. Dr. Swackhamer also noted that Dr. Milford had provided editorial comments to clarify parts of the report. In addition, Dr. Milford found that the Panel's statement indicating that the scientific basis for the RPF approach was not well justified needed further clarification, and that the executive summary could be better organized. In addition, Dr. Swackhamer noted that Dr. Milford had asked for a clearer explanation of the Panel's argument that the RPF method was independent of mechanistic information.

Dr. Kim then responded to the SAB lead reviewer comments. She noted that clarifications could be incorporated into the report to address the comments. She indicated that the Panel had agreed with the RPF approach but had offered recommendations to improve it. She noted that in this regard, clarifying text could be included in the Panel's report. She noted that, as suggested by Dr. Roberts, the discussion of modes and mechanisms of action could be clarified. In addition, she noted that the discussion of the mixtures approach in the executive summary could be placed into context by including additional information that was in the body of the report.

Some of the lead reviewers commented that the editorial changes suggested by Dr. Kim would clarify the report. Dr. Roberts indicated that his comment concerning modes and mechanisms of action could be addressed by including a clarifying explanation in the report.

Dr. Swackhamer then asked other chartered SAB members for comments. The SAB had further discussion of the Panel's recommendation concerning the use of single dose studies to derive RPFs. The SAB also further discussed the Panel's recommendations concerning use of the RPF and mixtures approaches. An SAB member noted that the Panel should separately evaluate these approaches. He encouraged the Panel to present the case that a mixtures approach has advantages, and also encouraged the Panel to give EPA guidance about the future application of the approach. A member commented that the Panel's review provided many good recommendations future research. He noted that it was important to indicate which

recommendations were most important with regard to application of the current RPF approach. He also noted that it was important to provide a clear message to the Agency about the use of the RPF document. Another member noted that the report should indicate that the SAB had been asked to conduct this review.

Dr. Kim responded that additional discussion of the advantages of the mixtures approach could be included in the report. She reiterated her previous statement that the Panel did not recommend calculating RPFs using single dose studies but she noted that, as indicated in the report, scientific judgment would be needed in this regard. She also indicated that the Panel wanted to clearly state its conclusion that the RPF approach should be used, and that she would review the report to make sure that this was clearly indicated. She also noted that some SAB members had requested more information in the executive summary, and some had indicated that it should be shorter. Dr. Swackhamer responded that the executive summary should include the important points in the responses to the charge questions.

Dr. Swackhamer asked whether any members had additional comments. There were no further comments so Dr. Swackhamer asked for a motion on disposal of the report. She noted that the Board's quality review could result in: 1) approval of the report either as is or subject to editorial changes and review by the Chair, 2) approval of the report subject to re-review by designated Board members, or 3) return of the draft report to the authoring panel or committee for further work so that a revised report may be brought before the Board for a second quality review. A member moved that the report be approved subject to editorial changes and re-review by the lead reviewers as well as SAB members Drs. Thomas Burke and Terry Daniel. The motion was seconded. The Chair asked for a voice vote to approve the motion. The motion carried.

Dr. Swackhamer then thanked Dr. Kim and members of the SAB Panel for submitting a very a good report. The Designated Federal Office then adjourned the meeting.

Respectfully Submitted:

/Signed/

Dr. Thomas Armitage
SAB DFO

Certified as True:

/Signed/

Dr. Deborah L. Swackhamer
SAB Chair

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by committee members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the panel members. The reader is cautioned to not rely on the minutes represent final, approved, consensus advice and recommendations offered to the Agency. Such

advice and recommendations may be found in the final advisories, commentaries, letters, or reports prepared and transmitted to the EPA Administrator following the public meetings.

The following meeting materials are available on the SAB Web site, <http://www.epa.gov/sab>, at the [December 16, 2010 Chartered SAB Meeting page](#)

¹ Review of EPA's Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures (February 2010 Draft)

² Federal Register Notice Announcing the Meeting

³ Agenda

⁴ Preliminary Quality Review Comments from Members of the Chartered SAB and Board Liaison Members